

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. : 10/565,023 Confirmation No. 9012
Applicant(s) : Suokas, et al. Customer No. 26646
Filed: : July 18, 2006
Art Unit : 3734
Title: : SYNTHETIC, BIOABSORBABLE POLYMER MATERIALS AND
IMPLANTS
Examiner : J. Hornberger

Mail Stop RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF DR. PERTTI TORMALA

I, Pertti Tormala, Ph.D hereby declare as follows:

1. I received my Ph.D in polymer science from the University of Helsinki (Helsinki, Finland) in 1974. I also received a B.S. in medicine from the University of Helsinki in 1973. I was an Academy Professor and Head of Institute at Tampere University of Technology in Tampere, Finland from 1995 to 2005. I am currently professor emeritus at Tampere University of Technology. I am an author on over 1000 international publications and printed conference abstracts on polymer science and technology, focusing on biopolymers and their surgical applications. I am also an inventor on more than 200 U.S. and international patents and an inventor on several hundred patent applications describing the processing, structure, properties and medical or technical applications of synthetic polymers, ceramics and composite materials.

2. I am a named inventor on the above-referenced application. I have reviewed the above-referenced application; the Office Action of April 14th, 2009; and U.S. Patent No. 6,406,498 (“the ‘498 patent”), which was cited in the 4/14/09 Office Action and for which I am a named inventor.

3. The present claims are directed to a bioabsorbable device that comprises a bioabsorbable oriented polymer matrix and pharmaceutical agents dispersed in the matrix. The pharmaceutical agents are selected from the group consisting of antibiotics, anti-inflammatory agents, and anti-bacterial agents. These pharmaceutical agents are capable of retaining their solid particulate form in the melt-processing temperature of the matrix. This allows cavities to be induced around the solid particles as a result of orientation and mechanical solid state procesing of a mixture of the matrix and the pharmaceutical agents. These cavities result from inclusion of the particles of the pharmaceutical agents and, thus, if the pharmaceutical agents were not present during the solid state processing of the polymer matrix, no such cavities would form.
4. As shown by the present application, the inclusion of cavities around the pharmaceutical agents results in increased amounts of the agent being released during the first weeks after the bioabsorbable device is exposed to saline solution. (See page 22, lines 10-14). Thus, the inclusion of cavities around the pharmaceutical agent is not a trivial limitation of the claims.
5. Not all antibiotics, anti-inflammatory agents or anti-bacterial agents have the same melting temperatures. Similarly, not all polymers have the same melting temperatures. The present claims are only directed to those pharmaceutical agents and polymers that have melting temperatures such that the pharmaceutical agents retain their solid particulate form in the melt-processing temperature of the polymer matrices in which they are dispersed. In other words, the present claims cover antibiotics, anti-inflammatory agents, and anti-bacterial agents that have a higher melting temperature than the polymer in which they are dispersed so that these agents retain their solid form to allow cavities to be formed therearound during polymer processing.
6. The '498 patent only refers to antibiotics and other general classes of drugs without mentioning any specific properties of these agents. There is certainly no mention of the melt-processing temperature of these agents and since the type of pharmaceutical agents listed in the claims can have different melting temperatures, the mere reference to "antibiotics" in the '498 patent does not result in a description of antibiotics that have a melting temperature higher than the polymer in which they are dispersed. As such, the '498 patent does not disclose an express

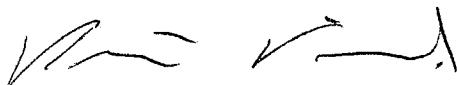
10/565,023
PATENT
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limitation of the present claims, which is pharmaceutical agents capable of retaining their solid particulate form in the melt-processing temperature of the polymer matrix.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: August 28, 2009

Signed


Pertti Tormala, Ph.D